REMARKS

The Amendments

Claim 4 is amended to remove the "neuornorm" term and thus address the 35 U.S.C. §112, second paragraph, rejection. It was believed that when this amendment was proposed in the previous After Final reply it was clear that it simplified the issues for appeal since it clearly renders moot the 35 U.S.C. §112, second paragraph, rejection made in the Final action. Thus, it is not clear why this amendment was refused entry per the Advisory Action. In any event, the requested amendment should now be entered.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Restriction Requirement

Upon filing this RCE, applicants reiterate their traversal of the restriction requirement originally set forth in the Office action mailed February 28, 2005. The restriction was alleged to be between Group I, claims 1-8, 36 and 37, drawn to compositions, kits and therapeutic methods using them, and Group II, claims 9-34, drawn to inhalants and methods of nebulization. It was alleged that the inventions were unrelated. Applicants respectfully disagree with the characterization of the claims and the allegation that these Groups are "unrelated." Claims 9-12 and 14- 34 are all drawn to compositions which are within the scope of claim 1. In fact, all of these claims depend, ultimately, upon claim 1. Since the compositions defined by claims 9-12 and 14-34 are all within the scope of claim 1, it is not reasonable to assert that the inventions here are unrelated. The compositions defined by

claims 9-12 and 14-34 are merely more defined embodiments all fully within the scope of claim 1 and requiring all the elements of claim 1. Thus, it is urged that the restriction should be withdrawn at least as to claims 9-12 and 14-34. Claim 13 is directed to a capsule containing the composition of claim 11 or 12. Thus, it is in a combination-subcombination relationship with the invention of Group I and, again, it is not reasonable to assert that the invention of claim 13 is "unrelated" to the invention of Group I. No basis is provided on the record to support a restriction between the combination-subcombination claims of claim 13 and Group I. For the above reasons, it is urged that the restriction as a whole should be withdrawn.

The Rejection under 35 U.S.C. §112, second paragraph

The rejection of claim 4 under 35 U.S.C. §112, second paragraph, is believed to be rendered moot by the amendment to claim 4.

The Rejection under 35 U.S.C. §103

The rejection of claims 1-8, 35 and 37 under 35 U.S.C. §103, as being obvious over Meissner (U.S. Patent No. 6,706,726) in view of Podolsky (US Pub. No. 2003/185838), is respectfully traversed.

The Advisory Action states that "Podolsky teaches the administration of neurokinin receptor antagonists in the treatment of COPD." This allegation is clearly unsupportable on the record. Podolsky teaches that specific trefoil peptide compounds may be used to treat lesions of the respiratory epithelium. Podolsky discloses that the lesions being treated can result from a wide variety of causes (see, e.g., page 1, paras. 0004 and 0010). Such lesions are not necessarily connected with COPD but are a symptom which can arise as a consequence of many of a variety of circumstances or diseases, for instance, from such varied

sources as surgical intervention or intubation or by inhaling smoke, etc. (see, e.g., page 3, para. 0032, of Podolsky). One of ordinary skill in the art is not taught by Podolsky that any of its trefoil peptides or second therapeutic agents are effective to treat COPD but merely a symptom which might arise from it or from any of a number of other varied sources. COPD is only in certain situations connected with lesions of the respiratory epithelium, i.e., lesions of the epithelium are not a general symptom in COPD. Further, lesions of the respiratory epithelium can also be caused by many different diseases and circumstances other than COPD. It is simply not true that Podolsky teaches use of its specific trefoil peptides to treat COPD.

Further, even if Podolsky did teach use of its specific trefoil peptides to treat COPD, it does not teach or suggest the combined use of a neurokinin receptor antagonist with an anticholinergic for treating COPD.

Meissner provides no teaching of combining its anticholinergics with a neurokinin receptor antagonist. Podolsky discloses that its specific trefoil peptides may optionally be used in combination with second therapeutic agents. Podolsky discloses a large variety of general second therapeutic agents which could possibly be used, i.e., anti-inflammatory agents, non-steroidal anti-inflammatory agents, antimicrobial agents, antihistamines, cholinergic receptor antagonists, neurokinin receptor antagonists, leukotriene receptor antagonists, decongestants, phosphodiesterase inhibitors and beta-adrenergic antagonists (see, e.g., page 1, para. 0012). One of ordinary skill in the art would not have been motivated by the reference teachings or have any other reason to combine one of the second therapeutic agents of Podolsky into the Meissner compositions or methods. Meissner is directed to methods and medicaments for treating COPD, whereas Podolsky is directed to methods and medicaments for treating lesions of the respiratory epithelium. As discussed above, these are

different methods. Further, even if treating lesions of the respiratory epithelium were considered to also treat COPD – which is not supported on the record – Podolsky still only suggests that its specific trefoil peptides are useful for treating lesions of the respiratory epithelium. Podolsky does not teach what effect the secondary agents may have or that they would be useful for treating lesions of the respiratory epithelium.

For the above reasons, applicants respectfully urge that the instant facts are not in line with the citation in the Office action to In re Kerkhoven. Podolsky does not suggest the use of their second therapeutic agents to treat COPD. Thus, there is no motivation or other reason to combine any one of the second therapeutic agents of Podolsky, e.g., an NK receptor antagonist, with the anticholinergics of Meissner to treat COPD. In Kerkhoven, there was a reason to combine the two components because both were taught for the same specific use. Such is not the case here.

Further applicants urge that the In re Burckel decision cited in the Office action (and also KSR International Co. v. Teleflex Inc., 550 U.S. _, 82 USPQ2d 1385 (2007)) are not applicable to the instant facts. Applicants recognize that the reason for combining reference teachings need not be expressly stated in the cited references. Applicants' argument is that no reason – whether explicit, implicit or from application of common sense (see KSR) – for making the combination alleged in the Office action finds sufficient support on record. The apparent reason for combining the reference teachings is that both teach compounds for treating COPD. As discussed above, however, this reason is not supported by the facts. Podolsky does not teach that either its trefoil peptides or second therapeutic agents should be used to treat COPD.

Even if one considered that Podolsky teaches treatment of COPD directly – which it clearly does not – one would not additionally conclude that the second therapeutic agents it teaches, e.g., NK receptor antagonists, would also be effective for treating COPD without the

trefoil peptides. Podolsky just teaches that the specific trefoil peptides are effective to treat the lesions of the respiratory epithelium. Podolsky does not state whether its second therapeutic agents are also useful for treating these lesions or have some other effect. One of ordinary skill in the art could not have a reasonable expectation that the second therapeutic agents, particularly a specific selected one of them, would be effective without being combined with the trefoil peptides which are the main focus of Podolsky.

Even if, contrary to all of the above reasons, one of ordinary skill in the art did have a reason to combine a second therapeutic agent of Podolsky into the Meissner compositions/methods, the claimed invention would still not be suggested. Podolsky teaches "neurokinin receptor antagonists" as only one broad category among a wide variety of possible second therapeutic agents. Given the broad teaching, one of ordinary skill in the art would not have been fairly directed to select this specific category of agent to combine with Meissner, particularly in view of the other distinctions discussed above. Further, Podolsky's teaching of "neurokinin receptor antagonists" does not point one of ordinary skill in the art to the specifically claimed invention, even if this category was selected. Podolsky does not teach, specifically, NK_1 antagonists (i.e., neurokinin receptor type 1 antagonists). There are at least three known neurokinin receptors types and nothing in the art points one of ordinary skill in the art to specifically select the NK_1 antagonists.

Further, both Meissner and Podolsky are silent as to the combined effect of an anticholinergic and NK_1 receptor antagonist. There is no suggestion that these compounds would be compatible or that their combination would be reasonably expected to succeed for treating a respiratory disease, particularly COPD, or for any other reason.

For all of the above reasons, it is urged that the combined teachings of the prior art fail to render the claimed invention obvious to one of ordinary skill in the art and the

rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the application is in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any additional fees necessary to filing this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/John A. Sopp/

John A. Sopp, Reg. No. 33,103
Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Date: May 28, 2008

Attorney Docket No. 01-1363

JAS/sb